DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 17, 2015

DSM Biomedical
Ms. Brianna Jordan
Regulatory Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K141738
Trade/Device Name: Medeor Matrix Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: January 15, 2015
Received: January 16, 2015

Dear Ms. Jordan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141738

Device Name
Medeor Matrix Wound Dressing

Indications for Use *(Describe)*
Medeor Matrix Wound Dressing is indicated for the management of topical wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears), and draining wounds.

Medeor Matrix Wound Dressing is intended for one time use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

Submitted By: DSM Biomedical
735 Pennsylvania Drive
Exton, PA 19341

Contact Person: Brianna Jordan
Regulatory Specialist
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Date Prepared: August 12, 2014

Device:

Trade Name:	**Medeor Matrix Wound Dressing**
Common/Usual Name:	Collagen Wound Dressing
Classification Name:	Dressing, Wound, Collagen
Classification Regulation:	N/A
Device Class:	Unclassified
Device Code:	KGN
Advisory Panel:	General and Plastic Surgery

Predicate Device: K112888: Meso Wound Matrix [Kensey Nash Corporation]
Reference Device: K091499, K103787: Medeor Matrix [Kensey Nash Corporation]

Device Description:

Medeor Matrix Wound Dressing, Acellular Dermal Matrix is a resorbable porcine dermis-derived dressing intended for the management of topical wounds. The device is sterilized by electron beam irradiation and supplied hydrated in a double layer package. The device is a prescription device for single use only.

Indications for Use:

Medeor Matrix Wound Dressing is indicated for the management of topical wounds including:

partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears), and draining wounds.

Medeor Matrix Wound Dressing is intended for one time use.

Technological Characteristics:

Medeor Matrix Wound Dressing is substantially equivalent in terms of indications for use, material composition, technological characteristics and performance characteristics to the predicate device, Meso Wound Matrix, [Kensey Nash Corporation] K112888. Medeor Matrix Wound Dressing and Meso Wound Matrix are decellularized, porcine derived extracellular matrices. The only difference is that Medeor Matrix Wound Dressing is comprised of porcine dermis and Meso Wound Matrix is comprised of porcine mesothelium.

Medeor Matrix Wound Dressing has identical material, technological and performance characteristics as the reference device, Medeor Matrix (hydrated version) [Kensey Nash Corporation] K091499, K103787.

Characteristic	**Medeor Matrix Wound Dressing (K141738)**	**Meso Wound Matrix (K112888)** ***(Predicate Device)***	**Medeor Matrix (K091499, K103787)** ***(Reference Device)***
Indications for Use	Medeor Matrix Wound Dressing is indicated for the management of topical wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined	Meso Wound Matrix is indicated for the management of topical wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined	Medeor Matrix is indicated for use in general surgical procedures for the reinforcement and repair of soft tissue where weakness exists including but not limited to defects of the thoracic wall, suture line

Characteristic	Medeor Matrix Wound Dressing (K141738)	Meso Wound Matrix (K112888) *(Predicate Device)*	Medeor Matrix (K091499, K103787) *(Reference Device)*
	wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears), and draining wounds. The device is intended for one time use.	wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears), and draining wounds. The device is provided sterile and for one time use.	reinforcement and muscle flap reinforcement; urogynecological surgical reinforcement (excluding transvaginal repair of pelvic organ prolapse) including but not limited to, rectal prolapse (excluding rectocele) using abdominal approach, vaginal prolapse (excluding transvaginal repair of pelvic organ prolapse), reconstruction of the pelvic floor using an abdominal approach (excluding transvaginal repair of pelvic organ prolapse), hernia repair; soft tissue reconstructive procedures including plastic and reconstructive surgical applications and for reinforcement of the soft tissues, which are repaired by suture or suture anchors, including but not limited to, rotator cuff, patellar, Achilles, biceps, quadriceps and other tendons. The

Characteristic	Medeor Matrix Wound Dressing (K141738)	Meso Wound Matrix (K112888) *(Predicate Device)*	Medeor Matrix (K091499, K103787) *(Reference Device)*
			device is not intended to replace normal body structure to provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair. The device is provided sterile and for one time use.
Origin	Porcine tissue	Porcine tissue	Porcine tissue
Device Characteristics	Resorbable single layer wound dressing	Resorbable single layer wound dressing	Resorbable single layer surgical mesh
Biocompatible	Yes	Yes	Yes
Reusable	Single Use Device	Single Use Device	Single Use Device
Shelf Life	3 years	2 years	3 years
Sterilization Method	E-Beam	Ethylene Oxide	E-Beam
Packaging	Double peel packages	Double peel packages	Double peel packages

Biocompatibility and Performance Data:

Biocompatibility testing, bench testing and characterization testing have been conducted to evaluate the biological safety and biomechanical performance characteristics of Medeor Matrix Wound Dressing.

Biocompatibility testing was completed on the finished sterile device in accordance with the requirements of *ISO 10993-1: 2009, Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process*. Testing included Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Genotoxicity, Hemocompatibility, Subacute Systemic Toxicity, and Chronic Systemic Toxicity. Other safety testing included a viral inactivation study and residual chemical assessment. Results indicate that the device's biocompatibility profile is acceptable.

Bench testing included hydration and suture testing. Testing results indicate that the device is equivalent to the predicate device and meets the requirements for its intended use.

Substantial Equivalence:

Pursuant to section 510(k), Medeor Matrix Wound Dressing is substantially equivalent to the predicate device Meso Wound Matrix (K112888) with regard to indication for use, material, technological characteristics, including principles of operation, and performance characteristics. Medeor Matrix Wound Dressing is identical in material, technological and performance characteristics as the reference device, Medeor Matrix (hydrated version) [Kensey Nash Corporation] K091499, K103787.